**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation** | **Master File No. 2:12-MD-02327**<br>**MDL 2327** |
| **THIS DOCUMENT RELATES TO ETHICON WAVE 4 CASES:**<br>***Identified in Exhibit A*** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF HARVEY A. WINKLER, MD**

Plaintiffs in the above-captioned consolidated cases respectfully move this Court to exclude the testimony of Harvey Winkler, M.D., a proffered expert witness for the Defendants, regarding Ethicon's TVT, TVT-Exact, Prolift, and Gynemesh PS mesh products. Dr. Winkler does not possess the necessary qualifications to render many of his opinions. Additionally, Dr. Winkler's opinions are not based on sufficient facts or data. Most importantly, he has not established that he followed a reliable methodology to reach many of his opinions.

Specifically, Dr. Winkler offers opinions regarding the *adequacy* of Ethicon's warnings in IFUs, but he lacks the requisite qualifications and has not reliably reviewed the actual regulations to testify regarding the adequacy of warnings. Despite the Court consistently excluding state-of-mind testimony, Dr. Winkler seeks to testify as to the state of mind of doctors and patients, including what he erroneously believes *all* doctors knew about these products. Accordingly, Plaintiffs respectfully request that the Court exclude Dr. Winkler's opinions and testimony as discussed herein.

**LEGAL STANDARD**

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

The function of the Court is to act as a gatekeeper when it comes to expert testimony: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" and it is incumbent upon the Court to "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993)). Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996). Additionally, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014) and *Sanchez v. Boston Sci. Corp.*, No. 2:1-cv-5762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014).

## ARGUMENT

The Court should prohibit Dr. Winkler, a urogynecologist designated as a Defense expert, from presenting a number of opinions about the mesh devices because he is unqualified and has not established that he has followed any reliable methodology.

**Dr. Winkler's Overreaching Opinions Exceed His Qualifications and Experience**

Dr. Winkler is a pelvic floor and reconstructive surgeon. However, he seeks to offer broad overreaching opinions that exceed his qualifications involving FDA regulations, biomechanical engineering, histopathology, and epidemiology. Dr. Winkler has not established that he is uniquely qualified in these areas by knowledge, skill, experience, training, or education. He has no direct training in any of these areas. Dr. Winkler has no direct personal experience in any of these specialties. Simply because Dr. Winkler reads literature in his private practice, he is no more qualified to make broad sweeping conclusions about the epidemiological evidence than an attorney who reads medical literature is qualified to provide expert testimony regarding surgical technique. More importantly, Dr. Winkler has not established that he followed a reliable methodology in reaching opinions in any of these areas. Dr. Winkler's expert testimony must be limited to areas where he is sufficiently qualified and has established followed a reliable methodology. His opinions that do not satisfy these requirements must be excluded.

### I. DR. WINKLER'S OPINIONS REGARDING THE *ADEQUACY* OF ETHICON'S WARNINGS SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED TO RENDER THESE OPINIONS AND HE FOLLOWED AN UNRELIABLE METHODOLOGY.

Dr. Winkler's seeks to testify that Ethicon provided *adequate* warnings in its IFUs. However, he is he is not qualified to offer opinions regarding regulatory compliance and he did not employ a reliable methodology to reach these opinions, in part, because he has not reliably

reviewed the regulatory or internal Ethicon requirements for warnings.[1] *See, e.g., In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2:12—md-02327, Doc. No. 2701 at 9-10 (S.D. W. Va. Aug. 31, 2016) (an expert "must possess additional expertise to offer testimony about what information should or should not be included in an IFU.") (internal citation omitted). Dr. Winkler's waffling explanations for his conclusion that Ethicon provided adequate warnings is not supported by any reliable basis – he simply is not an expert on these regulations and has not actually reviewed the applicable standards. Accordingly, his opinions related to the adequacy of Ethicon's warnings should be excluded in their entirety.

Dr. Winkler cannot articulate a reliable, consistent explanation for how he reached this opinion. When asked if his opinion regarding the adequacy of warnings is "based upon [his] experience as a physician or [his] interpretation of a specific federal regulation governing labeling," he testified that "It's my interpretation of the CFR that says you do not need to include commonly known adverse events." Transcript of Dr. Harvey Winkler Deposition on 3/12/2017, 8:49 a.m., 206:18-207:2 ("TVT dep.") (attached as Exhibit D). Later, he changed course and testified that his labeling opinions were instead based on both federal regulations and upon his own personal opinion as a physician. TVT dep. 209:19-210:11. Yet again, Dr. Winkler later flipped his explanation, "My standard for what needs to be in the IFU is based on the [] government regulations as opposed to guidelines." TVT dep. 221:22-222:2.

Dr. Winkler proclaimed, "I am an expert on FDA regulations when it comes to devices and implants for incontinence as well as for the pelvic floor, in my opinion." TVT dep. 197:21-198:2. Of course, there are no FDA regulations specifically regarding these mesh implants. Dr. Winkler

[1] Wave 4 Expert Report of Harvey A. Winkler, M.D., Regarding Gynemesh PS and Prolift, February 5, 2017 (attached as Exhibit B) ("Prolift Report"); Wave 4 Expert Report of Harvey A. Winkler, M.D., Regarding TVT and TVT Exact, February 5, 2017 (attached as Exhibit C) ("TVT Report").

additionally testified that he views himself as an expert regarding FDA requirements for product labeling. TVT dep. 198:3-7.

However, Dr. Winkler acknowledged he has no training in federal regulations. When directly asked if he had any training in federal regulations, he *instead* testified that he had training in using devices and developing devices – notably *not* training in federal regulations. TVT dep. 204:5-17. When directly asked again if he had any training in regulations, he admitted that he does not follow the regulations in his practice. He testified that that he teaches "regardless of what the government regulations are of what needs to be included or what does not need to be included [in product labeling]." TVT dep. 204:21-205:13.

More importantly, Dr.Winkler admitted he has not read all the federal regulations regarding product warnings. When specifically asked if he read the entire 21 CFR, he admitted, "No, I skimmed it." When asked how he decided which sections to actually read (rather than "skim"), he admitted, "I don't recall how I decided which ones were more pertinent to others." TVT 198:24-199:7.

Dr. Winkler has not reviewed the regulations and does not incorporate them in his practice. Dr. Winkler is simply not qualified to testify that Ethicon's warnings were adequate and he did not follow any reliable methodology in reaching his opinions.

## II. DR. WINKLER'S PERSONAL OPINIONS THAT ETHICON ACTED APPROPRIATELY ARE IRRELEVANT AND SHOULD BE EXCLUDED.

Dr. Winkler is a urogynecological surgeon. He is not an expert in industry practices or corporate compliance. In both of his reports, Dr. Winkler makes various statements regarding his opinions as to the appropriateness of Ethicon's corporate conduct. For example, he states, "it was appropriate for Ethicon to not introduce changes to the mesh too rapidly." TVT report at 28. Dr.

Winkler has not established that he has any qualifications regarding corporate or industry practices. Dr. Winkler has not established that he reviewed any industry standards governing corporate conduct or any of Ethicon's internal standard operating procedures. Because he lacks expert qualifications and has not followed any reliable methodology, he should not be allowed to testify as to his personal opinions of Ethicon's corporate conduct.

## III. DR. WINKLER'S OPINIONS REGARDING TVT-R LASER-CUT-MESH (LCM) ARE NOT BASED ON SUFFICIENT FACTS OR DATA.

Dr. Winkler opines that there is no difference between the TVT-R mechanically cut and TVT-R laser cut. *See* TVT report at 7. He has no personal experience using laser-cut TVT-R. He also admits there is no scientific evidence directly comparing TVT-R laser-cut-mesh to TVT-R mechanically-cut-mesh. Accordingly, he has no sufficient facts or data to support his opinion regarding laser-cut-mesh, and this opinion should be excluded. *See In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2:12—md-02327, Doc. No. 2668 at 6 (S.D. W. Va. Aug. 26, 2016) (allowing Dr. Rosenzweig to testify regarding clinical differences between mechanical-cut and laser-cut products because he has extensive experience working with *both* products).

The explanation provided by Dr. Winkler in his written report for this opinion is that he has "implanted traditional TVT, mechanically cut and laser cut, and [has] not noticed a difference in complications." *Id.* However, he testified he had actually *never* used TVT laser cut. TVT dep. 56:24-57:1 ("Q: Did you use laser-cut TVT-R? A: Not that I recall."); 112:19-21 ("Q: you said you never used a laser-cut TVT-R; is that correct? A: I don't think that I have."). When asked to identify any study comparing TVT laser cut to TVT mechanically cut, he admitted, "I'm not aware of any study…" TVT dep. 174:18-19; ("Q: And you don't cite any study specifically comparing TVT machine-cut to TVT laser -cut, correct? A: Yeah…") TVT dep. 173:21-24.

Dr. Winkler simply has no basis for opining on the differences between TVT-R machine cut and laser cut, and these opinions should be excluded.

## IV. DR. WINKLER UNRELIABLY ASSUMES HE KNOWS WHAT ALL DOCTORS AND PATIENTS KNOW.

The Court has "consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury's fact-finding duties." *See, e.g., In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2:12—md-02327, Doc. No. 2727 at 7 (S.D. W. Va. Sept. 2, 2016). However, in his reports, Dr. Winkler repeatedly offers his unreliable opinions regarding what *he thinks* other doctors know.

For example, Dr. Winkler unreliably guesses that all surgeons are "acutely aware" of different success rates associated with these products, that all risks and surgical complications for stress urinary incontinence procedures are "commonly known," and that surgeons are aware of the specific risks associated with the TVT procedure. TVT report at 23 ("…surgeons are acutely aware that certain types of patients may have higher success rates…"); at 35 ("surgical risks and complications for stress incontinence procedures are commonly known…"); and at 41 ("Subsequently, surgeons are aware of the consequences of chronic pain and dyspareunia developing after any incontinence procedure, including a sling procedure TVT."). Dr. Winkler even goes so far as to assume **patients** are aware of the risks to surgery. TVT Report at 40. These unreliable assumptions are pervasive throughout both his TVT and Prolift reports.

In deposition, Dr. Winkler explicitly admitted that he has no basis for these overreaching assumptions, "[w]ould I know what everyone else is thinking? Absolutely not." TVT dep. 264:17-18. He further testified, "Once again, I can't opine on what people know or don't know." TVT dep. 265:9-10. Dr. Winkler admitted no evidence exists to support his assumption. Transcript of Dr. Harvey Winkler Deposition dated 3/12/2017, 4:10 p.m. 220:12-14 (attached as Exhibit E)

("Prolift dep.") ("I'm not aware of any particular study of asking what doctors exactly know or don't know.").

Dr. Winkler acknowledged that different doctors, of course, have different knowledge based on different training, different personal experience, different specialties, reading different medical journals, and attending different medical seminars. TVT dep. 255:9-15; TVT dep. 256:18-23; TVT dep. 272:12-19. He also admitted he is not aware of any evidence showing what all doctors are aware of. TVT dep. 267:1-7; Prolift dep. 267:1-7.

Because Dr. Winkler has no reliable basis for these opinions and consistent with the Court's earlier rulings, these opinions should be excluded.

## V. DR. WINKLER'S VAGUE AND OVERLY-BROAD OPINIONS THAT THE MESH PRODUCTS ARE "AS SAFE" AS ALTERNATIVES IS NOT THE PRODUC OF A RELIABLE SCIENTIFIC METHODOLOGY AND NOT BASED ON SUFFICIENTLY RELIABLE DATA.

Dr. Winkler seeks to testify that the mesh products are "as safe" as alternative treatments. To reliably conclude that two treatments have the same risk for complications, he necessarily must figure out what the complication rates are for each treatment. Dr. Winkler admits this was necessarily the required methodology, "[m]y understanding is that I'm testifying of [sic] whether or not the complication rates are higher with what was commonly known out there and **what the rates are as opposed to the absolute rates of the surgical procedures**." TVT dep. 291:24-292:5.(emphasis added). However, Dr. Winkler has not followed a reliable methodology to assess the complication rates for any of the mesh products or the alternative treatments.

Dr. Winkler describes two bases for his vague, overly broad opinions that mesh products are "as safe" as alternative treatments. First, he asserts that he has reached this opinion based on his self-described "anecdotal" personal experience. Prolift dep. 133:2-134:22. However, Dr.

Winkler admits he is simply "guessing" at to the complication rates his patients experienced. TVT dep. 116:6-13. Second, he asserts that he reached his opinion based on his review of the medical literature. However, Dr. Winkler's "review of the literature" is merely a shotgun-blast recitation of selective findings, from various articles with zero scientific methodology to analyze or synthesize the data. In fact, he admits he did not perform *any* mathematical analysis to assess the data and instead simply picked "a middle number." Prolift dep. 98:4-8. This vague opinion should be excluded as he has not established that he followed a reliable methodology or that his opinion is based on sufficient facts or data.

**A. Dr. Winkler's "Anecdotal" Personal Experience Is Not a Reliable Basis for Broad Expert Opinions.**

Dr. Winkler asserts that his opinion regarding the safety of these devices is based on his personal experience. Of course, the Court does not automatically have to allow an expert's vague and overly-broad opinion simply because the expert asserts his opinion is based on personal experience. Instead, the *expert* has the burden to first demonstrate that he followed a reliable methodology and his opinions are based on sufficient facts on data. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("…the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). Here, Dr. Winkler readily admits he has no reliable method for assessing his own personal experience, does not reliably track any of this information, and is instead guessing.

Dr. Winkler simply has no reliable method for estimating how many of his patients suffered complications. When asked if he had any reliable methodology to calculate how many of the women in whom he implanted slings suffered an erosion, he admitted, "I don't have a reliable way." TVT dep. 116:23-117:4. When asked if he had any reliable methodology to calculate how

many of the women suffered dyspareunia, he again admitted, "I don't have that number available to me." TVT dep. 117:5-117:10. Similarly, Dr. Winkler admitted he had no reliable methodology for estimating how many women suffered chronic pain. TVT dep. 117:11-17.

Therefore, Dr. Winkler admits that any estimate of how many of his patients in whom he implanted slings suffered from complications such as exposures or erosions is *simply a guess*. TVT dep. 116:6-13 ("…Yeah, it's a guess.") Since he admits he has no reliable way of estimating complication rates based off his personal experience, he just assumes that the rate is what is in the literature, "I don't have my own estimate. I would go with pretty much what's in the literature, to be honest with you." TVT dep. 115:20-22.

Dr. Winkler's opinion that his personal experience demonstrates the mesh devices are "as safe" as alternatives is not based on sufficient data, is not the product of a reliable methodology, and should be excluded.

### B. Dr. Winkler's Unscientific Guess-work Regarding the Literature is Not a Reliable Methodology.

Dr. Winkler's opinions regarding the literature is equally troublesome. Without providing any statistical analysis, Dr. Winkler simply guesses as the "middle ground" of various findings to conclude that the complication rates for mesh are the same as alternative treatments. Prolift dep. 98:4-8; Prolift dep. 100:14-17. Then, he selectively relies upon findings from certain publications when they support his opinion and ignores findings and conclusions from those very studies when they contradict his opinions. This is the hallmark of litigation science and represents an unreliable methodology.

Dr. Winkler admits he cited numerous findings from the body of literature in his reports, but also that he did not perform any reliable statistical analysis to synthesize those findings. Prolift dep. 58:12-17; Prolift 100:14-17. Dr. Winkler further admits that due to the numericity of findings

and his inability to perform any meaningful numerical analysis, he cannot be "pinned down to a number." Prolift dep. 100:14-101:2. In fact, Dr. Winkler admitted that he does not know "the true rates of either to an exact number." Prolift dep. 103:5-9. However, despite this lack of knowledge, he somehow reaches the conclusion that "there's no differences in rates for [alternatives] versus transvaginal mesh." Prolift dep. 103:5-9. This is simply not reliable.

Instead of performing any mathematical analysis, Dr. Winkler must rely upon the analysis as performed by statisticians and epidemiologists. Prolift dep. 58:18-23. However, he selectively relies on findings from some studies when they support his opinions, and then ignores contrary findings and conclusions from the same studies and other studies he was aware of. For example, Dr. Winkler admits the 2016 Cocrhane review is the highest level of evidence, he has no criticisms of the study, and the study deserves more deference. Yet, he simply ignores the adverse findings from this important study and ignores its conclusions which disagree with his litigation opinions. Prolift dep. 59:16-20; 62:16-24; 63:13-20; 64:7-65:19.

For example, the 2016 Cochrane review concluded that "The risk-benefit profile means that transvaginal mesh has limited utility in primary [prolapse repair] surgery." Prolift dep. 69:17-70:13. The 2016 Cochrane review further concluded, "While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there's currently no evidence to support this position." Prolift dep. 72:4-15. Importantly, Dr. Winkler testified that he *agreed* with the Cochrane's conclusions that there is no evidence to support the use of mesh in high risk patients and that the use of mesh has limited utility in primary surgery. Prolift dep. 72:12-14; 75:17-76:8. Of course, nowhere in Dr. Winkler's reports does he state that the mesh should not be used in primary surgery or that there is no evidence to support its use in high risk patients, which contradicts his opinion the mesh is "as safe" as other treatments.

In sum, Dr. Winkler admits he has no idea what the complications rates are for the patients he has operated on. Instead, he admits he simply assumes his personal experience matches the rates in the literature. His personal experience is thus not a reliable basis for his opinion. However, Dr. Winkler's opinion regarding the complication rates of mesh and non-mesh procedures is equally problematic. He admits he performed no analysis to synthesize the numerous findings, and instead guessed as to a "middle ground." Worse, he selectively cites to findings that support his opinions but ignores contrary findings. Dr. Winkler has not established that he followed any reliable methodology in assessing the literature. Accordingly, his opinion that mesh is "as safe" as alternatives should be excluded.

## VI. DR. WINKLER'S OPINION THAT MESH DEGRADATION STOPS ONCE THE MESH IS IMPLANTED IS NOT SUPPORTED BY SUFFICIENT FACTS OR DATA.

Dr. Winkler seeks to testify that the mesh does not degrade, that mesh degradation after implantation is not clinically significant, and that the mesh degradation stops once implanted. It is unclear how all three of these opinions can reliably co-exist. However, regarding the third conflicting opinion that degradation stops after implantation, Dr. Winkler simply has no evidence to support his assertion and he admits as much. When asked what studies support this opinion that degradation or particle loss stopped once mesh is implanted, he admitted, "I don't have any studies, that I'm aware of…" TVT dep. 176:24-177:18. All of Dr. Winkler's conflicting opinions regarding degradation are suspect, but his opinion that mesh stops degrading after implantation has zero scientific basis and should be excluded.

## CONCLUSION

Dr. Winkler does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. Additionally, Dr.

Winkler has not established that he followed a reliable methodology in reaching his vague and overly broad opinions or that he has sufficient reliable facts or data to support them. For the reasons stated above, Plaintiffs respectfully request this Court exclude Dr. Winkler's opinions.

Respectfully submitted this 13th April, 2017.

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the list of participants registered to receive service in this MDL.

/s/ Shea N. Shaver